PMA Decisions Rendered for September 2007

APPLICATION NUMBER / DATE of APPROVAL	DEVICE TRADE NAME	COMPANY NAME CITY, STATE, & ZIP	DEVICE DESCRIPTION / INDICATIONS
PMA Original Approvals			
P040040 **9/7/07**	The Amplatzer® Muscular VSD Occluder	AGA Medical Corporation Golden Valley, MN 55427	Approval for The Amplatzer® Muscular VSD Occluder. The device is indicated for use in patients with a complex ventricular septal defect (VSD) of significant size to warrant closure (large volume left to right shunt, pulmonary hypertension and/or clinical symptoms of congestive heart failure) who are considered to be at high risk for standard transatrial or transarterial surgical closure based on anatomical conditions and/or based on overall medical condition. High risk anatomical factors for transatrial or transarterial surgical closure include patients: 1) Requiring left ventriculotomy or an extensive right ventriculotomy; 2) With a failed previous VSD closure; 3) With multiple apical and/or anterior muscular VSDs (“Swiss Cheese Septum”); or 4) With posterior apical VSDs covered by trabeculae.
PMA Supplemental Approvals			
P820003/S081 **9/28/07** **Real-Time**	Medtronic Model 5348 and Model 5388 External Pulse Generators	Medtronic, Inc. Cardiac Rhythm Disease Management Shoreview, MN 55126	Approval for minor design changes and internal component updates to Medtronic Model 5348 and Model 5388 External Pulse Generators.
P910023/S132 **9/11/07** **180-Day**	Promote Models 3207-36 and 3207-30	St. Jude Medical Cardiac Rhythm Management Division Sylmar, CA 91342	Approval for adding the wireless communication between the programmer and the implantable devices.
P950022/S040 **9/6/07** **Real-Time**	Riata STS Optim Lead Models 7120, 7121, 7122, 7130 and 7131	St. Jude Medical Cardiac Rhythm Management Division Sylmar, CA 91342	Approval for distal tip changes to the Riata ST Optim lead family. The device, as modified, will be marketed under the trade name Riata STS Optim Lead Models 7120, 7121, 7122, 7130 and 7131, and are indicated for use as transvenous, steroid eluting, right ventricular dual and single defibrillation coil leads with compatible pulse generators.
P960011/S011 **9/13/07** **Real-Time**	Biolon™ 1% Sodium Hyaluronate	Ferring Pharmaceuticals, Inc. Suffern, NY 10901	Approval for a change in inflammation testing for bulk sodium hyaluronate from oxidative burst testing to an IL-6 ELISA method.

PMA Decisions Rendered for September 2007

APPLICATION NUMBER / DATE of APPROVAL	DEVICE TRADE NAME	COMPANY NAME CITY, STATE, & ZIP	DEVICE DESCRIPTION / INDICATIONS
P960016/S019 9/24/07 Real-Time	Safire Cardiac Ablation System	St. Jude Medica Atrial Fibrillation Division Minnetonka, MN 55345	Approval for labeling modifications that allows: 1) the IBI-1500T6 and T9 Cardiac Ablation Generators (equipped with temperature monitoring) to be used with the Safire Bi-directional Ablation Catheter and 2) the extension cables (previously approved under P960016/S016 for use with the IBI-1500T6) be used with the IBI-1500 T9 RF Generator.
P970012/S028 9/18/07 Real-Time	Kappa 400	Medtronic, Inc. Shoreview, MN 55126	Approval for a change to the XM485 and XM486 wire bond terminal blocks found in Medtronic Kappa 700, Kappa 900, EnPulse, Adapta/Versa/ Sensia, Sigma, 350 Series, Thera/Prodigy, Kappa 400, and InSync-II Implantable Pulse Generator and Cardiac Resynchronization Therapy Pacemaker (CRT-P) Families.
P980035/S075 9/18/07 Real-Time	Kappa 700, Kappa 900, EnPulse, Adapta/Versa/ Sensia, Sigma, and Medtronic 350 Series	Medtronic, Inc. Shoreview, MN 55126	Approval for a change to the XM485 and XM486 wire bond terminal blocks found in Medtronic Kappa 700, Kappa 900, EnPulse, Adapta/Versa/ Sensia, Sigma, 350 Series, Thera/Prodigy, Kappa 400, and InSync-II Implantable Pulse Generator and Cardiac Resynchronization Therapy Pacemaker (CRT-P) Families.
P010015/S031 9/18/07 Real-Time	InSync III	Medtronic, Inc. Shoreview, MN 55126	Approval for a change to the XM485 and XM486 wire bond terminal blocks found in Medtronic Kappa 700, Kappa 900, EnPulse, Adapta/Versa/ Sensia, Sigma, 350 Series, Thera/Prodigy, Kappa 400, and InSync-II Implantable Pulse Generator and Cardiac Resynchronization Therapy Pacemaker (CRT-P) Families.
P030054/S050 9/11/07 180-Day	Current ICD Models 1207-36, 1207-30, 2207-36 and 2207-30	St. Jude Medical Cardiac Rhythm Management Division Sylmar, CA 91342	Approval for adding the wireless communication between the programmer and the implantable devices.